K102768

DEC - 2 2010

SECTION 3 – 510(k) SUMMARY

DATE PREPARED: September 17, 2010

OWNER/OPERATOR:

Firm: Hologic, Inc.
Address: 6100 Technology Center Drive
Indianapolis, IN 46278
Phone #: 317-344-7500
Fax #: 317-344-7697
Registration #: 3003862400

CONTACT:

Primary Contact from September 20-October 1
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Director, Quality and Regulatory Affairs
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Indianapolis, IN 46278
Phone: 317-344-7630
E-mail: heidi.strunk@hologic.com

Primary Contact after October 1
Alyssa M. Lobo
Senior Quality and Regulatory Consultant (a full-time employee of Hologic, Inc.)
Hologic, Inc.
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Phone: 317-344-7532
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DEVICE NAME:

Classification Name:	Marker, Implantable Radiographic
Common/Usual Name:	Tissue Site Marking System
Proprietary Name:	SecurMark Biopsy Site Marking System
Device Class:	Class II
Description:	Implantable Clip
Number:	NEU
21 CFR Ref:	878.4300
Performance Standard:	None established

PREDICATE DEVICES:

510(k) Number	Device Name	Device Manufacturer	Location
K062528	Tissue Site Marking System	Hologic, Inc. (formerly Suros Surgical Systems, Inc.)	Indianapolis, IN

Section 3.1 – Description of the Device

The SecurMark Biopsy Site Markers provide the user with the ability to mark the location of the cavity where a breast biopsy was performed. Radiographic marking allows physicians to locate biopsy cavities should a follow-up lumpectomy or re-biopsy be necessary.

The SecurMark Biopsy Site Marker is a sterile, single patient use device comprised of a single, permanent biocompatible titanium or stainless steel marker surrounded by a bioabsorbable suture-like material and a deployment device.

The deployment device consists of a rigid cannula, handle, rigid push rod, spring, and plunger. The marker is located at the distal end of the deployment device. The marker is used in conjunction with a biopsy device. The biopsy devices available for use with the SecurMark markers are offered in different needle gauge sizes and lengths. In order to be compatible with their respective biopsy devices, the biopsy site marker deployment devices may be available in multiple size offerings.

The hand-held deployment device is utilized for both introducing the marker into the breast and depositing the marker into the biopsy cavity. The deployment device is manually operated and has limited contact with the patient. After the physician has appropriately positioned the deployment device, the physician manually depresses the plunger of the deployment device to deposit the marker in the intended location.

The permanent marking components of the SecurMark Biopsy Site Markers are available in different geometric shapes. In the event that two or more biopsy sites need to be marked, the user has the option to use a different shape of marker in each biopsy location. Each marker shape can be discerned under stereotactic (x-ray) imaging.

The permanent markers are classified as magnetic resonance (MRI) conditional at 3.0 Tesla field strength or less. The marker, when present in a patient undergoing an MRI procedure at 3.0 Tesla or less, will not create an additional hazard or risk with respect to magnetic field-related interactions, movement/dislodgement or heating.

The SecurMark Biopsy Site Markers should be used only by physicians trained in open or percutaneous biopsy procedures.

Section 3.2 – Intended Use

The SecurMark Biopsy Site Marking System is intended for use with the manual method of deployment. It can be visualized under various imaging modalities such as ultrasound, x-ray, magnetic resonance, direct visualization, and others. This system is intended for single patient use only. The Tissue Site Marking System is indicated for the permanent radiographic marking of sites in soft tissue.

Section 3.3 – Description of Device Modification

The modifications that are the subject of this 510(k) submission are as follows:

Modification to Permanent Marking Component Shape
The biopsy site markers that were cleared in K062528 specified markers that were cylindrical or "bow tie" shaped. The marking components that are the subject of this submission are shaped in one-hole, two-hole, or three-hole designs. See Section 3.5 for illustrations of the different marker shapes.

Modifications to Instructions for Use (IFU)
The Instructions for Use for the SecurMark Biopsy Site Markers that were cleared in K062528 address use of the biopsy site marker device only with other Hologic devices.

It has come to Hologic's attention that users who place Hologic biopsy site markers under ultrasound guidance sometimes utilize other non-Hologic biopsy devices and accessories, such as an introducer, (also referred to as a coaxial), prior to placement of the markers. Hologic's current IFU does not address the use of the biopsy site markers with any other company's biopsy devices and/or accessories.

In order to further guide users on the safe use of the Hologic biopsy site marker device, the proposed Instructions for Use has been modified to provide information to users regarding the dimensions of other devices that may be compatible with Hologic's biopsy site markers. The proposed new Instructions for Use are provided in Section 4.2.

Section 3.4 – Comparison of 510(k) Cleared Tissue Site Marking Systems

	SecurMark Biopsy Site Marking System (this 510(k) application)	**Tissue Site Marking System K062528** (cleared)
Indicated Use	The Tissue Site Marking System is indicated for the permanent radiographic marking of sites in soft tissue.	IDENTICAL
Bioabsorbable Marker Material	Glycoprene II® Monofilament (PLA/PGA)	IDENTICAL
Permanent Marker Material	Titanium (Grade 2) or 316 Stainless Steel	IDENTICAL
Supplied Sterile	YES	IDENTICAL
Sterilization Method	Gamma Irradiation	IDENTICAL
Sterilization Dose	25kGy-50kGy	IDENTICAL
Sterility Assurance Level (SAL)	10^{-6}	IDENTICAL
Single Patient Use	YES	IDENTICAL
Deployment Device Materials	Cannula: Stainless Steel, Titanium, or similar materials	IDENTICAL
	Handle: Polycarbonate or similar materials	IDENTICAL
	Spring: Stainless Steel or Beryllium Copper	IDENTICAL
Deployment Device Manufacturing Methods	Manufactured by Hologic, Inc.	IDENTICAL
Packaging Materials	High Impact Polystyrene (HIPS) Tray and foil pouch	IDENTICAL
Shelf Life	1 Year	IDENTICAL
Method of Marker Deployment	Manual	IDENTICAL
Dimensions		
Deployment Device	Overall Length: 5.934"	IDENTICAL
Bioabsorbable Marker	Length: 0.591" Center Diameter: 0.110" Closure Diameter: 0.044"	IDENTICAL
Permanent Marker Shapes (See Section 3.5 Device Illustrations for images)		
1st Shape	One-hole	Cylinder
2nd Shape	Two-hole	"Bow tie"
3rd Shape	Three-hole	Item not available

Section 3.4 – Comparison of 510(k) Cleared Tissue Site Marking Systems, continued

	SecurMark Biopsy Site Marking System (this 510(k) application)	Tissue Site Marking System K062528 (cleared)
Permanent Marker Dimensions		
1st Shape	Length: 0.100" Width: 0.037" Thickness: 0.010"	Length: 0.070" Diameter: 0.036"
2nd Shape	Length: 0.087" Width: 0.037" Thickness: 0.010"	Length: 0.075" Width: 0.036" Height: 0.036"
3rd Shape	Length: 0.094" Width: 0.037" Thickness: 0.010"	Item not available

Similarities between device and legally marketed devices

The similarities between the subject of the 510(k) submission and the previously cleared 510(k) device include:

1. Indications for Use
2. Intended Use
3. Scientific technology
4. Sterilization dose and method
5. Deployment device materials
6. Marker Materials
7. Deployment device manufacturing site and methods
8. Biocompatibility
9. Shelf Life
10. Supplied sterile for single patient use

Differences between device and legally marketed devices

Currently, the SecurMark Biopsy Site Identification system that is cleared under K062528 is different from the subject of this 510(k) application only in that:

1) The permanent marker components from K062528 are available in two shapes: cylinder and "bow tie." The markers that are the subject of this application are available in three shapes that feature one, two, or three openings.
2) The Instructions for Use for the currently marketed biopsy site markers do not provide users with any language to provide guidance if a customer chooses to use a non-Hologic introducer (co-axial) when placing the biopsy site marker under ultrasound visualization.

The new permanent marker shapes provide users with additional options for marking biopsy site locations. Each new shape is discernable from the other new shapes and from other Hologic marker shapes. The new wording in the IFU will give general guidance to users if they choose not to use a Hologic introducer when placing a Hologic biopsy site marker under ultrasound.

All other aspects of the subject of this 510(k) submission are the same as the legally marketed devices. No changes are made in the intended use or the fundamental scientific principles of the previously cleared devices.

Conclusion

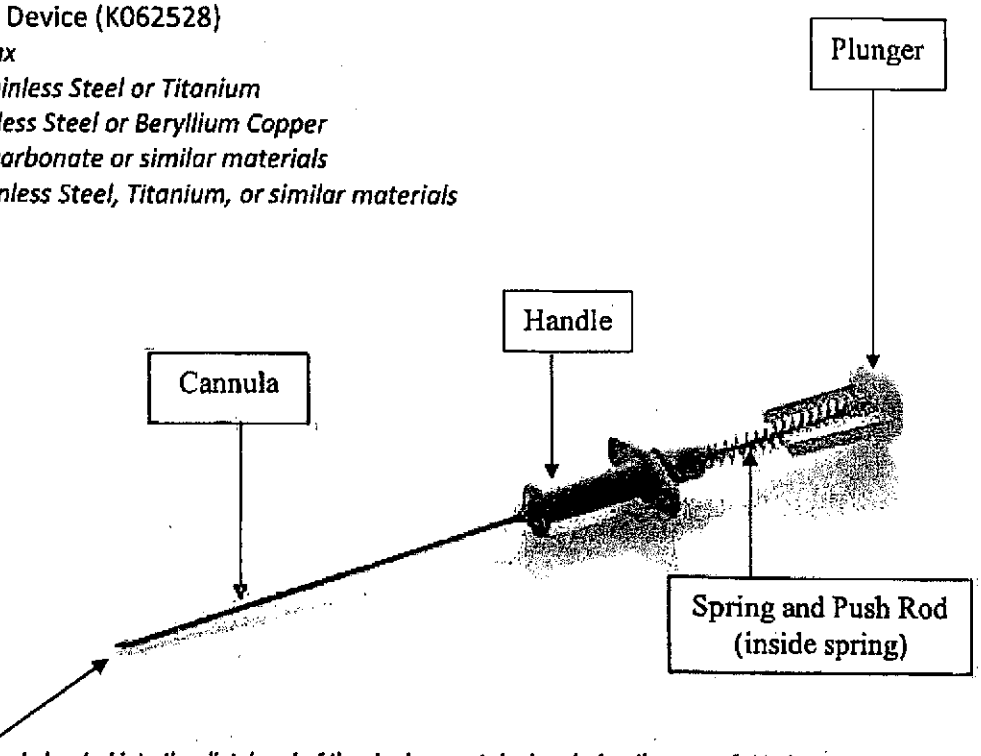
Based on the information presented in this Special 510(k) submission, the SecurMark Biopsy Site Marking System is substantially equivalent to the presently marketed Hologic, Inc. Tissue Site Marking System (K062528). No new safety or efficacy questions are raised with the SecurMark Biopsy Site Marking System that is the subject of this submission.

Section 3.5 – Device Illustrations

Assembled Deployment Device
Identical to the deployment device cleared in K062528

Device	Overall Cannula Length
SMark-U-ss1	5.934"
SMark-U-ss2	5.934"
SMark-U-ss3	5.934"

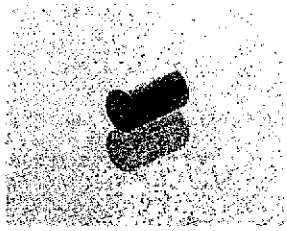
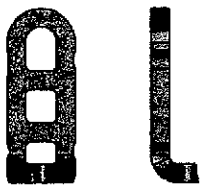
Deployment Device (K062528)
Plunger: Pebax
Push Rod: Stainless Steel or Titanium
Spring: Stainless Steel or Beryllium Copper
Handle: Polycarbonate or similar materials
Cannula: Stainless Steel, Titanium, or similar materials

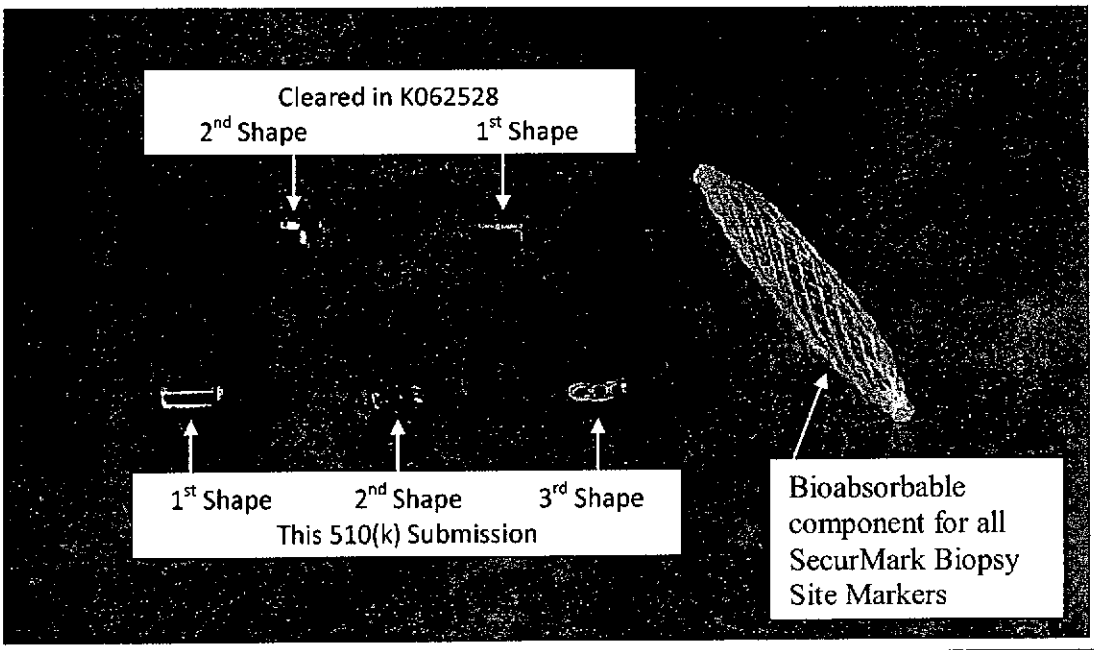


The marker is loaded into the distal end of the deployment device during the manufacturing process.

Marker (Cleared in K062528)
Bioabsorbable Component – PLA/PGA (Glycoprene II)
Permanent Component – 316 Stainless Steel or Titanium

Section 3.5 – Device Illustrations, continued

	SecurMark Biopsy Site Marking System (this 510(k) application)	Tissue Site Marking System K062528 (cleared)
Permanent Marker Images		
1st Shape	One-hole 	Cylinder 
2nd Shape	Two-hole 	"Bow tie" 
3rd Shape	Three-hole 	Item not available



Section 3.6 – Stereotactic Images

The stereotactic (x-ray) image below shows the new marker shapes compared to the previously cleared SecurMark Biopsy Site Marker permanent marking components.

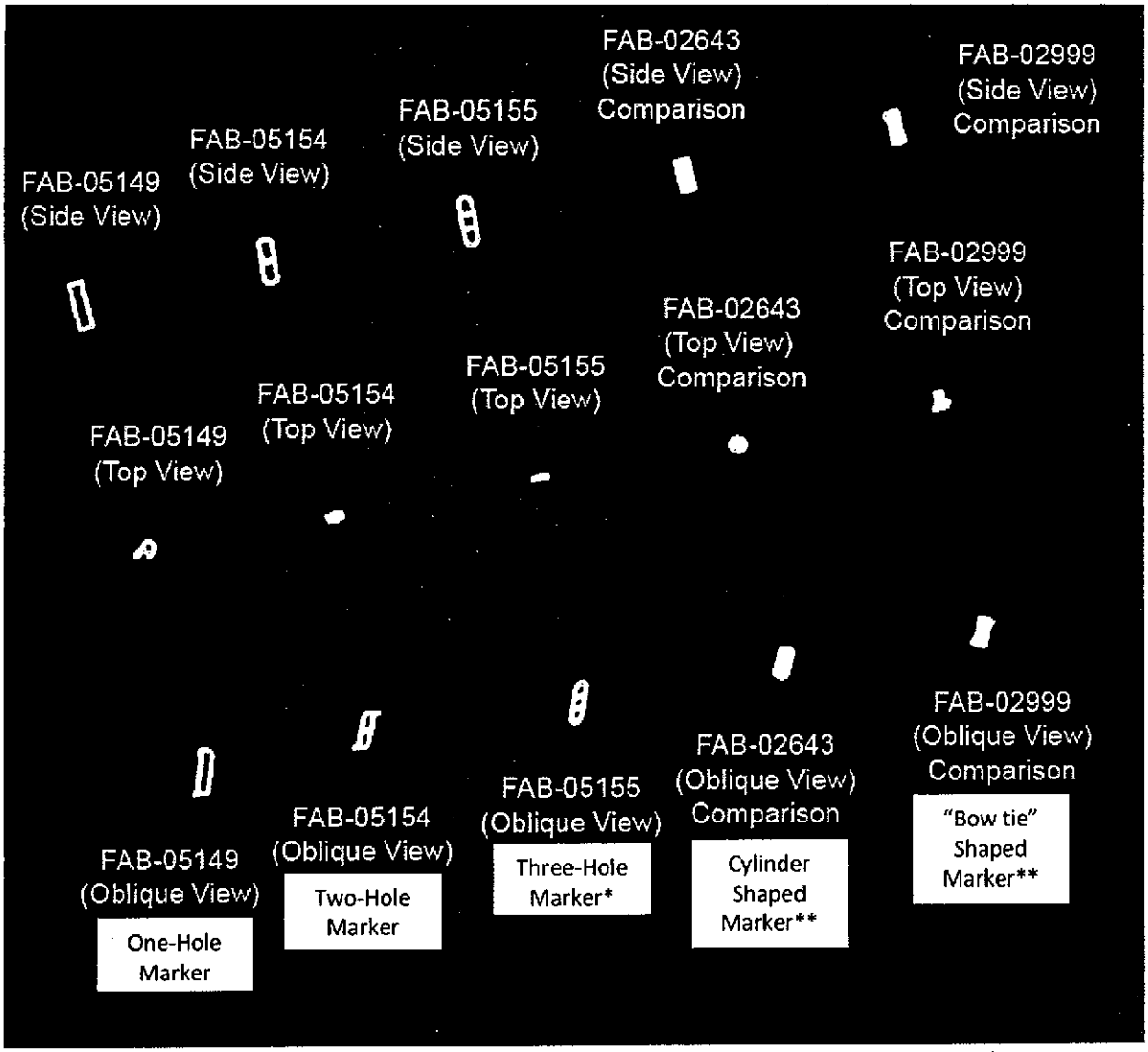


Image from VER-03109

*FAB-05155, the new three-hole marker, has since been modified to form a "J" shape. See images on previous page for illustration.

** Previously cleared under K062528.

Section 3.7 - Packaging

Packaging Materials

Packaging Component	Material
Pouch	RFP-048
Tray	White High Impact Polystyrene (HIPS)

Drawings of the packaging materials are included in the following pages.

After the SecurMark Biopsy Site Markers have been placed into trays and sealed in pouches, they are labeled and placed into boxes. There are ten SecurMark Biopsy Site Markers and one Instructions for Use (IFU) manual packaged in each box. Markers are sold to customers in case quantities; they are not sold individually.

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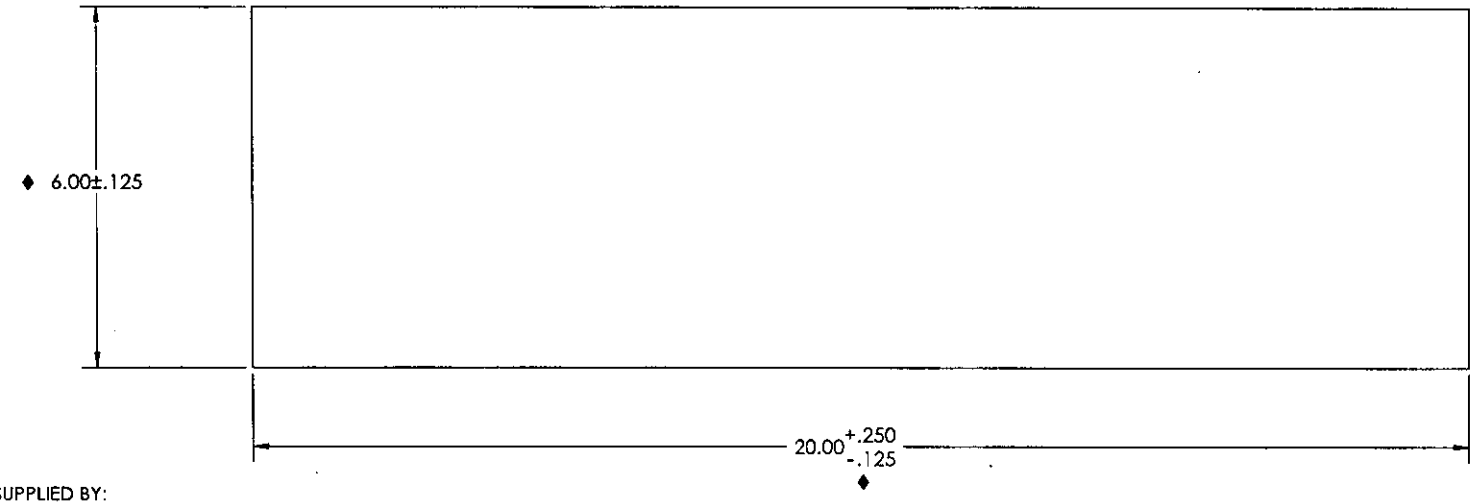
REVISIONS
SEE AGILE FOR REVISION HISTORY



PART AS SUPPLIED BY:
AMCOR

PART SPECIFICATIONS:
1.♦ MATERIAL: RFP-048 = 48 GA PET/15LB WLDPE/70GA FOIL(DI)/10LB LDPE/60 GA BIAX NYLON/10 LB LDPE/2MIL PEELABLE (LFM-417)
2. MOISTURE VAPOR TRANSMISSION RATE (MTVR): .02
3. AVERAGE PULL STRENGTH OF EACH SEAL TO BE 1 LB WITH A 0.70 LB MINIMUM.
4. SUPPLIER MUST PROVIDE CERTIFICATE OF ANALYSIS FOR SEAL INTEGRITY.
5. LOOSE FOREIGN MATTER STANDARDS:
   A. MAXIMUM PARTICLE SIZE: 1 mm.
   B. MAXIMUM NUMBER OF PARTICLES: 3 PER 20 INCHES.

NOTES:
1. SUROS ENGINEERING APPROVAL REQUIRED FOR ALL DIMENSIONAL AND/OR MATERIAL CHANGES. SUROS PURCHASING TO BE NOTIFIED IN WRITING OF ANY REQUESTED CHANGES.
2. THIS PART AND/OR DRAWING EXISTS IN AN ELECTRONIC DATABASE
3.♦PARTS TO BE CLEAN AND FREE OF OIL, GREASE, DEBRIS, AND BURRS
4.♦DENOTES CRITICAL DIMENSION AND/OR SPECIFICATION
5. CRITICAL DIMENSIONS AND/OR SPECIFICATIONS REPORT REQUIRED WITH EACH MANUFACTURING LOT
6.♦PARTS TO BE SHIPPED/STORED DOUBLE BAGGED IN TALC-FREE POLY BAGS.

DIMENSIONS INCLUDE THICKNESS OF PLATING. ALL EXTERNAL THREADS TO BE CLASS 2A BEFORE PLATING AND CLASS 2 AFTER PLATING. ALL INTERNAL THREADS TO BE CLASS 2B UNLESS OTHERWISE SPECIFIED.

DO NOT SCALE DRAWING
ALL DIMENSIONS ARE IN INCHES
VARIATIONS ON FINISHED DIMENSIONS UNLESS OTHERWISE MARKED

BASIC DIMENSIONS	2 PLACE DECIMALS	3 PLACE DECIMALS
UP TO 6	± .02	± .005
ABOVE 6 TO 24	± .03	± .010
ABOVE 24	± .06	± .015
ANGULAR DIMENSIONS ± 1/2 DEG		

SIGNATURES ON FILE | REV 003

NAME: **POUCH, BIRD CAGE FOIL (SHORT)**

DRAWN BY: L.FLUKER 09-21-07
DESIGNED BY: B. ZIMMER 01-22-07

MATERIAL: SEE PART SPEC

SUROS COMPASSIONATE TECHNOLOGIES
A HOLOGIC COMPANY

PART NO: **PKG-00151**

B SIZE | SHEET 1/1

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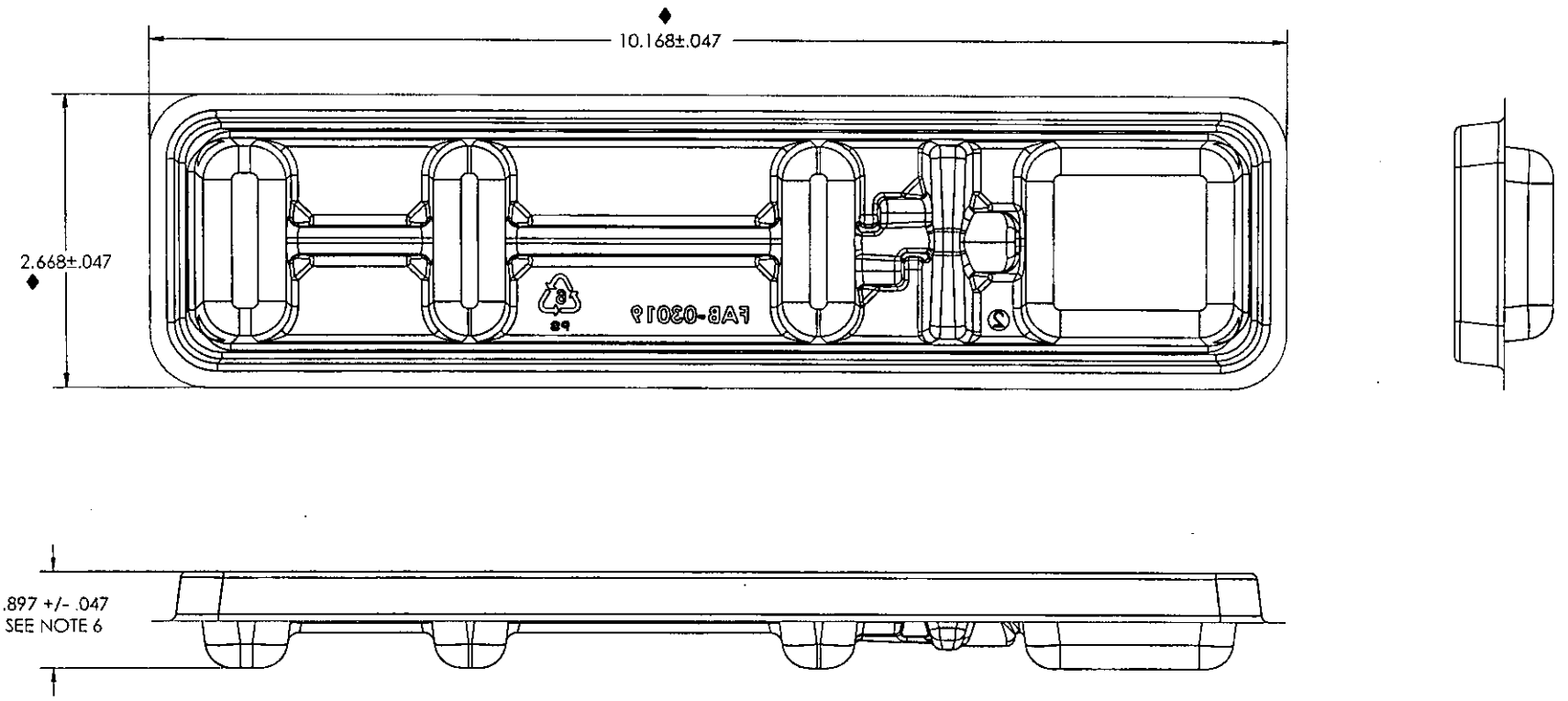
REVISIONS
SEE AGILE FOR REVISION HISTORY



NOTES:
1. SUROS ENGINEERING APPROVAL REQUIRED FOR ALL DIMENSIONAL AND/OR MATERIAL CHANGES. SUROS PURCHASING TO BE NOTIFIED IN WRITING OF ANY REQUESTED CHANGES.
2. THIS PART AND/OR DRAWING EXISTS IN AN ELECTRONIC DATABASE
3. PARTS TO BE CLEAN AND FREE OF OIL, GREASE, DEBRIS, AND BURRS
4. ♦DENOTES CRITICAL DIMENSION AND/OR SPECIFICATION
5. CRITICAL DIMENSIONS AND/OR SPECIFICATIONS REPORT REQUIRED WITH EACH MANUFACTURING LOT
6. DEPTH DIMENSION INCLUDES MATERIAL THICKNESS. MODEL DOES NOT REPRESENT MATERIAL THICKNESS.
7. ♦PARTS TO BE LABELED WITH THE QUANITY, SUROS PART NUMBER, AND VENDOR LOT NUMBER.
8. ♦PARTS TO BE SHIPPED/STORED DOUBLED BAGGED IN TALC-FREE POLY BAGS.
9. ♦VERIFY MATERIAL CERTIFICATION.

DIMENSIONS INCLUDE THICKNESS OF PLATING. ALL EXTERNAL THREADS TO BE CLASS 2A BEFORE PLATING AND CLASS 2 AFTER PLATING. ALL INTERNAL THREADS TO BE CLASS 2B UNLESS OTHERWISE SPECIFIED.

DO NOT SCALE DRAWING ALL DIMENSIONS ARE IN INCHES VARIATIONS ON FINISHED DIMENSIONS UNLESS OTHERWISE MARKED		
BASIC DIMENSIONS	2 PLACE DECIMALS	3 PLACE DECIMALS
UP TO 6	± .02	± .005
ABOVE 6 TO 24	± .03	± .010
ABOVE 24	± .06	± .015
ANGULAR DIMENSIONS ± 1/2 DEG		

SIGNATURES ON FILE | REV 001

NAME: **MARKER TRAY, UNIVERSAL SHORT**

DRAWN BY: L.FLUKER 09-21-07
DESIGNED BY: NA NA

MATERIAL: .030 HIPS 10

SUROS COMPASSIONATE TECHNOLOGIES
A HOLOGIC COMPANY

PART NO: **FAB-03019**

B SIZE | SHEET 1/1

Section 3.8 – Design Control Activities Summary

Modifications from Predicate Devices	Risk (from DFMEA)	Verification / Validation Activities	Acceptance Criteria	Results/Justification
Permanent marker components are shaped differently than those cleared in K062528	Product Performance	X-ray testing	New marker shapes must be discernable from other new marker shapes and current Hologic SecurMark marker shapes	Met acceptance criteria
	Product Performance (deployment of marker)	Simulated use	Deployment device must accommodate marker and deploy marker as intended.	Met acceptance criteria
IFU has been updated to provide general guidance for use of the biopsy site marker with non-Hologic introducer (coaxial) devices	Incompatible geometries	Tolerance analysis	Biopsy Site Marker must be able to be inserted into an introducer (coaxial) with specific minimum and maximum dimensions	Minimum introducer (coaxial) cannula inner diameter dimension established. Maximum introducer (coaxial) cannula length established.
	Product Performance	Simulated Use	Biopsy site marker deployment device must be geometrically compatible with introducers (coaxial) that meet the length and diameter criteria set by the Tolerance Analysis	Hologic biopsy devices tested with multiple introducer (coaxial) devices. Biopsy Site Markers met acceptance criteria

No new safety or efficacy questions are raised with the SecurMark Biopsy Site Marking System that is the subject of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Hologic, Inc.
% Ms. Alyssa M. Lobo
Senior Quality and Regulatory Consultant
6100 Technology Center Drive
Indianapolis, Indiana 46278

DEC - 2 2010

Re: K102768
Trade/Device Name: Biopsy Site Marking System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: November 11, 2010
Received: November 23, 2010

Dear Ms. Lobo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

HOLOGIC

CLARITY OF VISION

SECTION 2 – STATEMENT OF INDICATIONS FOR USE

DEC - 2 2010

Indications for Use

510(k) Number (if known): K102768

Device Name: Biopsy Site Marking System

Indications for Use: The Tissue Site Marking System is indicated for the permanent radiographic marking of sites in soft tissue.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter-Use___
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102768